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PATENT
2801-013.SP

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of		Before the Board of Appeals	
Ignatius Loy BRITTO		Appeal No.:	
Appl. No.:	09/506,838	Group:	1619
Filed:	February 18, 2000	Examiner:	R. BAWA
Conf.:	8929		
For:	METERED DOSE INHALER FOR BECLOMETHASONE DIPROPIONATE		

APPEAL BRIEF TRANSMITTAL FORM

Assistant Commissioner for Patents
Washington, D.C. 20231:

September 6, 2001

Sir:

Transmitted herewith is an Appeal Brief (in triplicate) on behalf of the Appellants in connection with the above-identified application.

☐ The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. 1.8.

A Notice of Appeal was filed on July 6, 2001.

☐ Applicant claims small entity status in accordance with 37 C.F.R. § 1.27

The fee has been calculated as shown below:

☐ Extension of time fee pursuant to 37 C.F.R. §§ 1.17 and 1.136(a) -

☒ Fee for filing an Appeal Brief - $310.00 (large entity).

☒ A check in the amount of $310.00 is attached.

☐ Please charge Deposit Account No. 02-2448 in the amount of $0.00. A triplicate copy of this sheet is attached.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Gerald M. Murphy, Jr., #28,977

GMM/MWM/gml
2801-0136P

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

(Rev. 01/22/01)

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A P P E A L B R I E F

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For: METERED DOSE INHALER FOR BECLOMETHASONE DIPROPIONATE

BRIEF ON BEHALF OF APPELANTS

Honorable Commissioner for Patents
Washington, DC 20231

September 6, 2001

Sir:

This is an Appeal from the Final Rejection of claims 22, 24-28, 30-32, 34, 39-50, 52 and 54 in the above-identified application, which claims were finally rejected in the Office Action mailed April 6, 2001.

I. REAL PARTY IN INTEREST

This application is assigned to GlaxoWellcome, Inc. Due to a corporate merger and corporate reorganization, the application is now owned by SmithKline Beecham, which is related to Glaxo SmithKline, Inc. The assignment of the application to

GlaxoWellcome, Inc. was recorded on October 22, 1998 at Reel 9543, Frame 0291.

II. RELATED APPEALS AND INTERFERENCES

There is a related appeal concerning Application No. 09/506,834 filed on February 18, 2000. This related application is handled by the same Examiner as the present application. There are no related interferences pending.

III. STATUS OF CLAIMS

The Examiner has finally rejected claims 22, 24-28, 30-32, 34, 39-50, 52 and 54. Claims 22, 24-28, 30-32, 34, 39-50, 52 and 54 are set forth in the attached Appendix. The rejection of claims 22, 24-28, 30-32, 34, 39-50, 52 and 54 are hereby appealed.

IV. STATUS OF AMENDMENTS

The Amendment under 37 C.F.R. §1.111 was filed on January 5, 2001 and entered into the record. Appellants have filed an Amendment under 37 C.F.R. §1.116 on September 5, 2001 to cancel claim 53. Appellants expect the after final amendment to be entered, since it simplifies matter under appeal.

V. SUMMARY OF THE INVENTION

The present invention is directed to a metered dose inhaler (MDI; see page 2, lines 22-24 of the specification) having part or all of its internal surfaces coated with a coating comprising a polymer blend comprising (a) one or more fluorocarbon polymers in combination with (b) one or more non-fluorocarbon polymers. The MDI contains an inhalation medicament formulation comprising a medicament and a fluorocarbon propellant. The coating minimizes drug deposition on the can wall and ensures consistent delivery of medication in aerosol from the MDI (see page 2, lines 9-12 of the specification). The use of the claimed polymer blend also improves adhesion of the coating on the can wall (see page 7, lines 17-22 of the specification) while at the same time minimizing the above described undesirable deposition of the drug on the can wall.

VI. ISSUES

1. Claims 22, 24-28, 30-32, 34, 39-50, 52 and 54 stand rejected under 35 U.S.C. §112, first paragraph, as based on a disclosure which is not enabling. The Examiner has identified an element that he alleges is critical or essential to the practice of the invention.

2. Claims 22, 24-28, 30-32, 34, 39-50, 52 and 54 stand rejected under 35 U.S.C. §101 as claiming the same invention as that of claims of prior U.S. Patent Nos. 6,149,892 and 6,143,277.

Therefore, two main issues remain for argument: the alleged enablement question and the alleged statutory double patenting question.

VII. GROUPING OF CLAIMS

The Honorable Board of Patent Appeals and Interferences is requested to give separate consideration to the groups of claims.

35 U.S.C. §112 Issues

Group I - Claims 22, 24-28, 30-32, 34, 39-44, 48-50, 52 and 54, Issue 1

Group II - Claims 45-47, Issue 1

35 U.S.C. §101 Issues

Group III - Claims 22, 24-28, 30-32, 34, 39-50, 52 and 54, Issue 2

VIII. ARGUMENTS

Group I - Issues under 35 U.S.C. §112

Claims 22, 24-28, 30-32, 34, 39-44, 48-50, 52 and 54 stand rejected under 35 U.S.C. §112, first paragraph, as based on a disclosure, which is not enabling.

The Examiner has raised concerns that the broadest claims, claims 22 and 52, do not recite limitations that are "critical" to the practice of the invention. More specifically, the Examiner alleges that the coating thickness of the fluorocarbon polymer is a feature that must be in claims 22 and 52 for the present invention to be enabled. The Examiner alleges that without such a limitation in claims 22 and 52, a skilled artisan would suffer an undue burden of experimentation. Appellants disagree with this assertion.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Cortright, 49 U.S.P.Q. 1464, 1466 (CAFC 1999) *quoting*, In re Marzocchi and Horton, 439 F.2d, 223, 169 U.S.P.Q. 367, 369 (CCPA 1971).

For example, on page 7, first paragraph, Appellants discuss in a general sense the coating thickness of the fluorocarbon polymers. Appellants disclose a broad range and narrower ranges of preferred embodiments. A skilled artisan would understand the broad concept of coating a metered dose inhaler can from the present disclosure. Furthermore, Appellants are not required to limit their invention to preferred embodiments as disclosed in the Examples. There is no statement in the specification that the numerical ranges concerning coating thickness are critical to practice of the claimed invention.

The Examiner must set forth a *prima facie* case that sets forth that there is a reason to doubt the truth of Appellants' disclosure. The Examiner has not set forth any argument questioning the truth of the disclosure concerning any subject matter; thus, the laws that govern the examining of the U.S. Patent application indicate that the rejection is improper.

Group II - Issues under 35 U.S.C. §112

Claims 45-47 stand rejected under 35 U.S.C. §112, first paragraph, as based on a disclosure, which is not enabling.

Claims 45-47 clearly recite ranges for coating thickness that are enabled on page 7, first paragraph. Therefore, claims 44-47 should not have been included in the instant rejection.

GROUP III - ISSUE UNDER 35 U.S.C. § 101

Claims 22, 24-28, 30-32, 34, 39-50, 52 and 54 stand rejected under 35 U.S.C. §101 as claiming the same invention as that of claims of prior U.S. Patent Nos. 6,143,277 and 6,149,892.

U.S. Patent No. 6,143,277

Claim 1 of U.S. Patent No. 6,143,277 claims a MDI comprising a drug formulation of "salmeterol" and a fluorocarbon propellant, wherein the MDI has a certain fluorocarbon blend coated on the inner surface thereof. Claims 22 and 52 of the present invention claims a MDI comprising a medicament formulation of a "medicament" and a fluorocarbon propellant. Claims 22 and 52 of the present invention clearly have a different scope from the invention claimed in U.S. Patent 6,143,277, which is limited to salmeterol. None of the remaining rejected claims are limited to salmeterol. To establish statutory double patenting, the claims must have the same scope of elements. Clearly, the instant claims are broader than claim 1 of U.S. Patent No. 6,143,277. Therefore a statutory double patenting rejection cannot stand.

Appellants filed a Terminal Disclaimer March 7, 2001 disclaiming any term beyond the term of U.S. Patent 6,143,277.

U.S. Patent No. 6,149,892

The claims of U.S. Patent No. 6,149,892 are directed to a metered dose inhaler containing an inhalation drug formulation of "beclomethasone dipropionate" (BDP). Thus, U.S. Patent No. 6,149,892 has a limitation, which is not present in claims 22, 24-28, 30-32, 34, 39-50 and 52 of the present application. Claims 22, 24-28, 30-32, 34, 39-50 and 52 of the present application are directed to a metered dose inhaler with an inhalation medicament formulation containing a medicament.

Concerning claim 54 of the present application, which is dependent on claim 22, the limitations of this claim differ from the claims of U.S. Patent No. 6,149,892. Instant claim 22 recites a Markush group limitation for the one or more fluorocarbon polymers and one or more non-fluorocarbon polymers; thus claim 54 has these limitations. The only claim that possesses these limitations in U.S. Patent No. 6,149,892 is claim 43, but claim 43 also contains a limitation to coating thickness, which is an added limitation over claim 54. Therefore, claim 54 of the present application has different elements than any claim in U.S. Patent No. 6,149,892.

Therefore, a statutory double patenting rejection cannot stand. Appellants will consider submission of a Terminal Disclaimer to disclaim the patent term beyond the term of U.S. Patent No. 6,149,892 should this be necessary for allowance.

Conclusion

The Honorable Board of Patent Appeals and Interferences is respectfully requested to reverse the rejection of the claims.

The required Appeals Brief fee under 37 C.F.R. §1.17(c) in the amount of $310.00 is attached hereto.

If the Examiner has any questions regarding the above matters, please contact Applicants' representative, Mark W. Milstead (Reg. No. 45,825), in the Washington, metropolitan area at the telephone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By: _____ #32,081

Gerald M. Murphy, Jr.
Reg. No.: 28,977

P. O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

GMM/MWM/gml

APPENDIX

CLAIMS UNDER APPEAL

22. A metered dose inhaler, comprising:

a can having part or all of its internal surfaces coated with a polymer blend comprising (i) one or more fluorocarbon polymers comprising monomeric units made from one or more monomers selected from the group consisting of tetrafluoroethylene, hexafluoropropylene, perfluoroalkoxyalkylene, and vinylidene fluoride in combination with (ii) one or more non-fluorocarbon polymers selected from the group consisting of a polyamide, a polyimide, a polyamideimide, a polyethersulphone, a polyphenylene sulfide, and an amine-formaldehyde thermosetting resin;

a can in communication with a drug metering valve; and

an inhalation medicament formulation, comprising a medicament formulated with a fluorocarbon propellant, said fluorocarbon propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane or 1,1,1,2,3,3,3-heptafluoro-n-propane and combinations thereof.

24. The metered dose inhaler according to claim 22, wherein said medicament formulation further comprises a surfactant.

25. The metered dose inhaler according to claim 22, wherein said medicament formulation further comprises a polar solvent.

26. The metered dose inhaler according to claim 22, wherein said medicament formulation comprises 0.01 to 5 % w/w of a polar cosolvent based on the weight of propellant.

27. The metered dose inhaler according to claim 25, wherein the polar solvent is ethanol.

28. The metered dose inhaler according to claim 22, further containing a medicament formulated with a fluorocarbon propellant and 0.01 to 5 % w/w of a polar cosolvent based on the weight of the propellant, said medicament formulation is substantially free of surfactant.

30. The metered dose inhaler according to claim 22, wherein the fluorocarbon propellant is 1,1,1,2-tetrafluoroethane.

31. The metered dose inhaler according to claim 22, wherein said can is made of metal and wherein part or all of the internal metallic surfaces are coated.

32. The metered dose inhaler according to claim 31, wherein the metal is aluminum or an alloy thereof.

34. The metered dose inhaler according to claim 22, wherein said one or more fluorocarbon polymers is selected from the group consisting of polytetrafluoroethylene, perfluoroalkoxyalkylene, and perfluorinated ethylene propylene copolymer.

39. The metered dose inhaler according to claim 22, wherein said non-fluorocarbon polymer is a polyethersulfone.

40. The metered dose inhaler according to claim 34, wherein said fluorocarbon polymer is polytetrafluoroethylene.

41. The metered dose inhaler according to claim 34, wherein said blend comprises perfluorinated ethylene propylene copolymer and polyethersulfone.

42. The metered dose inhaler according to claim 34, wherein said blend consists of polytetrafluoroethylene and polyethersulfone.

43. The metered dose inhaler according to claim 22, wherein said one or more fluorocarbon polymer is made from monomeric units comprising perfluoroalkoxyalkylene.

44. The metered dose inhaler according to claim 22, wherein said one or more fluorocarbon polymers is made from monomeric units comprising perfluorinated ethylene propylene copolymer.

45. The metered dose inhaler according to claim 22, wherein the thickness of said coating is 1 μm to 1 mm.

46. The metered dose inhaler according to claim 22, wherein the thickness of said coating is 1 μm to 100 μm.

47. The metered dose inhaler according to claim 22, wherein the thickness of said coating is 1 μm to 25 μm.

48. The metered dose inhaler according to claim 31, wherein said coating is applied to said internal surface of a preformed can.

49. The metered dose inhaler according to claim 31, wherein said coating is applied by spray coating said polymer blend.

50. The metered dose inhaler according to claim 31, wherein said coating is applied by spray coating said polymer blend on the internal metallic surface of said can and curing said coating after it is sprayed.

52. A metered dose inhaler, comprising:

a can having part or all of its internal surfaces coated with a polymer blend comprising (i) one or more fluorocarbon polymers comprising monomeric units made from one or more monomers selected from the group consisting of tetrafluoroethylene, hexafluoropropylene, perfluoroalkoxyalkylene, and vinylidene fluoride in combination with (ii) one or more non-fluorocarbon polymers selected from the group consisting of a polyamide, a polyimide, a polyamideimide, a polyethersulphone, a polyphenylene sulfide and an amine-formaldehyde thermosetting resin;

a can in communication with a means for metering an inhalation medicament; and

an inhalation medicament formulation, comprising a medicament formulated with a fluorocarbon propellant, said fluorocarbon propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane or 1,1,1,2,3,3,3-heptafluoro-n-propane and combinations thereof.

54. The metered dose inhaler of claim 22, said medicament comprising beclomethasone dipropionate.